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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA – SAN JOSE DIVISION

05-80234 HRL

In re: WELDING ROD PRODUCTS LIABILITY LITIGATION	Case No.: Misc MDL Docket No.: 1535 (N.D. Ohio, Eastern Division)
Non-Party Movant: The Parkinson's Institute	**NON-PARTY THE PARKINSON'S INSTITUTE'S MEMORANDUM OF POINTS AND AUTHORITIES SUPPORTING MOTION BY TO QUASH SUBPOENAE DUCES TECUM** **Hearing Date:** **Dept.:** **Judge:**

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I.

PRELIMINARY STATEMENT

The Parkinson's Institute ("The Institute") – a non-party to this litigation – seeks this Court's protection to prevent the type of unwarranted imposition and burden that is proscribed by Federal Rule of Civil Procedure 45(c). Plaintiffs in some Ohio proceedings have subpoenaed an enormous volume of confidential and proprietary data compiled by researchers at The Institute over many years, at a cost exceeding $9,000,000. Most of the data has nothing to do with welders or the welding products industry. The Institute has already provided welding data to plaintiffs' counsel in response to a nearly identical subpoena served in 2004. The new subpoenas are duplicative, overbroad, extremely burdensome and seek data protected against disclosure by the research scholar's privilege, the physician-patient privilege, trade secrets law, regulations promulgated by the Department of Health and Human Safety and the provisions of the Health Insurance Portability and Accountability Act (HIPAA). Service of the subpoenas was also defective.

For each of these reasons, this Court should quash the subpoenas under Rule 45(c). In the alternative, The Institute respectfully requests that, pursuant to Rule 26(c), this Court enter a protective order denying the discovery requested.

II.

STATEMENT OF FACTS

A. Non-Party The Parkinson's Institute.

The Parkinson's Institute is an independent, non-profit research institute whose mission is to find the cause(s) and a cure for Parkinson's disease, and to provide the best possible treatment to those suffering from the disease. The Institute was founded in 1988 by Dr. J. William Langston, an internationally renowned researcher whose discovery in 1983 of the link between a compound known as MPTP and parkinsonism led to a new generation of basic and clinical research into Parkinson's disease. The Institute has grown from a handful of employees to a staff of almost 100 involved in three main activities: basic research, clinical research, and patient care. Scientists at The Institute have published over

450 research articles during their careers. See Declaration of Dr. Langston In Support Of Motion To Quash Subpoenas Issued Upon Non-Party The Parkinson's Institute ("Langston Decl.") at ¶¶ 2-4.

The Institute's medical research includes epidemiological studies and basic research. Dr. Caroline M. Tanner, is the Institute's Director of Clinical Research. During her 24-year medical career, Dr. Tanner has published two textbooks and a videotext, and authored or co-authored over 150 articles and research papers on the treatment, natural history, epidemiology, and etiology of Parkinson's disease and other movement disorders. ("Langston Decl." at ¶ 6)

The Parkinson's Institute is not a party to any lawsuit involving welders or the welding products industry. The Institute has not been retained as an expert by any party to such a lawsuit. The Institute has conducted and is conducting a variety of epidemiological studies which apparently are of interest to the plaintiffs here, but no party has participated in any way in the conduct of any study by The Institute. ("Langston Decl." at ¶ 7,15-16)

The Institute receives federal funding from the National Institute of Health (NIH), private individual donors, public and private foundations, including the Michael J. Fox Foundation, and pharmaceutical companies. The Institute has an impeccable record and reputation for trustworthy, unbiased treatment information and research on movement disorders. ("Langston Decl." at ¶ 5)

Much of the Institute's work has to do with epidemiological studies based on data assembled from subjects identified through the National Academy of Sciences/National Research Council World War II Veteran Twins Registry of 19,842 white male twins ("Twins Registry"). The Twins studies and related work have nothing to do with welding, the welding products industry or plaintiffs' lawsuit. ("Langston Decl." at ¶¶ 13)

The Institute is currently working on a study investigating whether there is any link between certain occupations and an increased risk of developing Parkinson's disease. This is a comprehensive, large-scale study based upon original data gathered from a number of subjects, not from data previously generated in other studies. This study was

funded by an unrestricted grant from the welding products industry. However, the welding products industry has had no input on the conduct of the study. (Langston Decl. at ¶ 7, 15.)

B. Plaintiffs' First Subpoena In 2004.

In or about October 2004, plaintiffs in the Ohio cases served a subpoena on The Institute. The 2004 subpoena sought every conceivable type of paper and electronic record associated in any way with 15 different studies, abstracts, supplements to meeting announcements and reviews, dating from 2004 back to 1990, whether in the possession of The Institute or various third parties affiliated or associated with The Institute, including its attorneys. (Langston Decl. ¶ 8, Exh. A)

To avoid the burden, expense and interference with The Institute's research activities represented by the 2004 subpoena, The Institute agreed to provide plaintiffs' counsel with a "deidentified" database spreadsheet for the only study dealing with the occupations reported by persons with Parkinson's disease. The database was provided in November 2004, subject to a stipulated protective order which acknowledged the Institute's proprietary interest in the data, required that it be kept confidential, and prohibited plaintiffs from using it for other studies or publications. The Institute understood that, in return for providing this data, the 2004 subpoena was withdrawn. (Langston Decl. ¶ 9; Stone Decl. ¶¶12-15, Exhs. E-H)

C. Plaintiffs' New 2005 Subpoenas.

On September 22, 2005, plaintiffs served two identical subpoenas on a receptionist at The Parkinson's Institute, one addressed to "The Parkinson's Institute", and a second addressed to "The Parkinson's Institute in Sunnyvale" (The "2005 Subpoenas"). (Langston Decl. ¶ 10, Exhs. B and C) These subpoenas are extremely similar to the 2004 subpoena. They seek every conceivable type of paper and electronic record associated in any way with 15 different studies, abstracts, supplements to meeting announcements and reviews, from 2004 back to 1989, in some cases predating the author's association with The Institute. (Langston Decl. ¶12, Exhs. B and C)

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The 2005 subpoenas seek primarily documents having nothing to do with the welding products industry, welding as an occupation or the relationship of welding and Parkinson's disease. The categories are a sweeping summary of most of the work done by the Institute over the past 16 years. Compliance would effectively impose a penalty on the Institute for the work it has done over the years. To the extent the subpoenas seek records for the occupational study currently underway, that would be the only study funded by the welding products industry. (Langston Decl., ¶¶ 12 – 13, Exhs. B and C)

The Institute estimates that compliance with the subpoenas would take 1675 hours of time by clinical, research and clerical staff at a total expense of approximately $125,000, not including fees and costs for assistance from attorneys. Compliance will take valuable resources and time away from important work directed toward finding effective therapies and a cure for Parkinson's disease and other movement disorders, and will compromise the Institute's future work. (Langston Decl. ¶11)

D. The Institute's Proprietary Records Were Compiled Through Years Of Research And At A Cost Of More Than $9,000,000.

The documents sought by the 2005 Subpoenas are the result of years of research by The Institute, especially Drs. Tanner and Langston. Most of the documents relate to studies and papers having to do with Parkinson's disease in twins, none of which involves the welding or the welding products industry. These studies are based on data assembled by The Institute based on subjects identified through the National Academy of Sciences/National Research Council ("NAS/NRC") World War II Veteran Twins Registry of 19,842 white male twins. (Langston Decl. at ¶ 12-13, Exhs. B and C) The data in this Registry is confidential and for academic use only, and producing this data would violate The Institute's confidentiality agreement with the NAS and NRC. (Ibid.) The Institute is also required by the Florida Department of Health and the National Death Index to keep certain data confidential. (Id. at ¶¶ 14-15) Compliance with the 2005 Subpoenas would require the Institute to violate its confidentiality agreements with these organizations.

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Over the past 10 years, the Institute has paid the NAS/NRC more than $400,000 for the use of the Twins Registry. Overall, the Institute has spent $5,937,354 generating and analyzing the data used for the original Twins study, and has spent an additional $3,370,138 generating and analyzing the data used in a subsequent twins study. Producing the information sought by the subpoenas would give plaintiffs the benefit of years of research and a $9,000,000 investment free of charge. (Langston Decl. ¶13)

E. The Institute's Records Are Confidential.

The Institute takes great pains to ensure the confidentiality of its data. For example, peer-review comments and drafts of articles relating to this data are maintained in confidence and are only disclosed to outside parties with express permission of the CEO of The Institute. (Langston Decl. at ¶ 19-20) All computer records are kept secret and are only accessible to other researchers at The Institute and their research colleagues. (Langston Decl. at ¶ 20) All employees and consultants involved in The Institute's studies must sign a confidentiality and non-disclosure agreement, and employees or consultants who terminate their affiliation with The Institute must return all confidential information to The Institute. Electronic and hardcopy data is secured by password and key, and no party other than medical researchers personally approved by The Institute's CEO is allowed access. (Langston Decl. at ¶ 21 – 27) These measures ensure that the Institute's data and research are kept secret.

F. Compliance With The 2005 Subpoenas Will Harm Subjects And Patients.

The Institute's research database contains private health information about hundreds of subjects. These subjects provide this private information conditioned on the Institute's promise that it will not be disclosed to third parties or used for other purposes. (Langston Decl., ¶17)

The Institute's research records also include patient information and medical histories. The patient records include information which, if disclosed, could be used to identify patients even if names are redacted. (Langston Decl., ¶¶18-19)

G. Compliance With The 2005 Subpoenas Will Harm The Institute.

Disclosure of the Institute's research data and tools could jeopardize its studies, delay publication, taint the data analysis and results, damage the integrity of its research process, and possibly prevent publication in a peer-reviewed journal altogether. (Langston Decl. at ¶ 29, 33) Disclosure of unpublished works would jeopardize The Institute's professional credibility, its future subject recruitment and its future funding. (Langston Decl. at ¶ 30, 36) Disclosure of research data prior to publication would give others the opportunity to publish before the Institute using its own work, resulting in a complete loss of years of research. (Langston Decl. at ¶ 31, 34)

H. The 2005 Subpoenas Were Not Served On The Institute's Authorized Agent.

1. The Institute's authorized agent for service of process is James B. Greer. (Langston Decl. ¶38, Exh. F) The 2005 Subpoenas were served on a receptionist. (Langston Decl. ¶10)

III.

ARGUMENT

A. Abusive Subpoenas Seeking A Non-Party's Confidential Records Are Properly Quashed.

Federal Rule of Civil Procedure 45(c) protects parties subject to subpoenas and specifically lists confidential research as protected from discovery:

> On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it . . . requires disclosure of privileged or other protected matter and no exception or waiver applies, or subjects a person to undue burden.
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> . . .
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> If a subpoena requires disclosure of a trade secret or other confidential research . . . or requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party . . . the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena . . . .

FED. R. CIV. PROC. 45(c). Plaintiffs' subpoenas seek research protected by Rule 45. The Rule is intended to provide "appropriate protection for the intellectual property of the non-

party witness . . . . A growing problem has been the use of subpoenas to compel the giving of evidence and information by unretained experts. [C]ompulsion to give evidence may threaten the intellectual property of experts denied the opportunity to bargain for the value of their services." Id., advisory committee's note (1991) (emphasis added).

Courts have enforced the Rule 45 proscriptions, even where the records sought might be relevant to issues in the case. In Statutory Committee Of Unsecured Creditors v. Motorola, Inc., 218 F.R.D. 325 (D.C.D.C 2003), investors brought an action against the dominant shareholder of a corporation for failure to disclose material information. The plaintiffs subpoenaed a non-party investment analyst's copyrighted studies, which had cost the analyst $600,000 to produce, seeking proof that the defendant's market prospects were not as bright as had been represented by the dominant shareholder. The analyst was neither a party nor a retained expert in the lawsuit. The district court quashed the subpoena, holding that the analyst's confidential records and copyrighted materials were protected by Rule 45(c)(3)(B)(ii):

> In a technocratic society, knowledge is an extraordinarily valuable asset.... [T]here is something unfair about the courts permitting their processes, such as the issuance of a subpoena, ...to take for free the product of an individual's diligence, research and expertise. (Id. at p. 326)

Here, the Institute's research records cost more than $9,000,000 to produce. Plaintiffs should not be allowed to conduct research using data that The Institute spent years gathering and analyzing. Plaintiffs should not be permitted to save the time and expense of conducting their own expert analysis by using the subpoena power to piggyback onto the research of a non-party, non-profit research organization.

Similarly, in Mattel Inc. v. Walking Mountain Productions, 353 F.3d 792 (9th Cir. 2003), the owner of the Barbie Doll sued a artist who used graphic and unflattering images of the doll in his photography. Mattel subpoenaed the San Francisco Museum of Modern Art, as well as the Guggenheim Museum in New York, to produce a burdensome volume of material unrelated to their display of the defendant's work. This Court quashed the subpoena, holding that "Rule 45 provides that the court from which the subpoena was

issued 'shall quash or modify the subpoena if it . . . subjects a person to undue burden.'" Mattel, 353 F.3d at 814 (citing FED. R. CIV. PROC. 45(c)(3)(A)(iv). Further, this Court found that the unreasonably broad subpoena was "abusively drawn" and "the fact that the two museums' only relation to this litigation was as employers of [the defendant's expert witness] led the court to conclude that the two subpoenas were served for the purpose of getting the museums to exert pressure on the witnesses not to testify." (Id. at pp. 813-14). The Ninth Circuit Court of Appeal affirmed this Court's decision, and its award of SFMOMA's attorney's fees incurred.

The welding plaintiffs' subpoenas here are no less abusive; and the conclusion that plaintiffs seek to discourage The Parkinson's Institute from taking on any further occupational studies regarding the risk of Parkinson's disease is equally warranted. This Court should quash the subpoenas consistent with Rule 45(c)'s purpose and intent.

In the alternative, this Court should grant relief from the subpoena under Federal Rule of Civil Procedure 26(c). That rule permits a Court to deny discovery when discovery would result in undue expense to the subpoenaed party or would result in the disclosure of confidential research:

> Upon motion by a party or by the person from whom discovery is sought . . . and for good cause shown, the court in which the action is pending or alternatively, on matters relating to a deposition, the court in the district where the deposition is to be taken may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:
>
> (1) that the disclosure or discovery not be had;
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> . . .
>
> (7) that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way; and

FED. R. CIV. PROC. 26(c) (emphasis added). Plaintiffs' subpoenas seek research protected under Rule 26. This Court should enter a protective order refusing the discovery sought in Plaintiffs' subpoenas.

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In addition to violating Rules 45 and 26, the subpoenas seek information protected under numerous federal statutes and privileges. Finally, service of the subpoenas was improper. For all of these reasons, this Court should quash the subpoenas or enter a protective order denying discovery.

B. This Court Has Jurisdiction To Quash The Subpoenas.[1]

The issuing Court has the authority to quash a subpoena. Rule 45(c)(3)(A) states, in pertinent part, that the "court by which a subpoena was issued shall quash or modify the subpoena if it . . . requires disclosure of privileged or other protected matter and no exception or waiver applies, or subjects a person to undue burden." FED. R. CIV. PROC. 45(c)(3)(A) (emphasis added). This is precisely the relief sought by The Institute. Further, courts have found that controversies regarding depositions of non-parties are decided in the court that issued the subpoena unless the non-party consents. Fincher v. Keller Industries, Inc., 129 F.R.D. 123, 125 (D. N.C. 1990).

C. The Subpoenas Impose Undue Burden And Expense On The Non-Party Institute.

The subpoenas demand that The Institute produce "all documents and data," "all paper and electronic files," "all notes, correspondence, memoranda, e-mail or other documents," "all analyses of any of the data" relating to fourteen research studies authored by researchers at The Institute. They also seek "all clinical data from any source" maintained by the Institute that relates to these studies, not to mention "a complete copy of all manuscripts, abstracts or other writings" maintained by the Institute that relates to these studies. The scope of the subpoenas is staggering.

The Institute is in the research business, not the litigation business. These subpoenas would require the Institute to stop researching the effects of Parkinson's

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[1] We understand that Judge O'Malley has issued a Standing Order Regarding Protocol Involving Disputes Before Other United States District Courts Concerning Enforcement Of Subpoenas, which provides that Judge O'Malley prefers to hear and resolve all discovery disputes that arise in other districts. A copy of Judge O'Malley's Standing Order is Exhibit J to the Stone Decl. filed herewith. The Parkinson's Institute nonetheless seeks the protection of this Court against being drawn into the Ohio litigation against its will.

Disease and instead concentrate its efforts on providing Plaintiffs with voluminous documents that bear no relation to Plaintiffs' allegations in the welding cases. (Langston Decl. at ¶ 11)

Rule 45(c)(1) provides that a party responsible for the service of a subpoena shall take "reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena." Plaintiffs have taken no such steps. Most of the information sought in the fourteen studies has nothing to do with welding. (Langston Decl. at ¶ 10) Only one study listed in the subpoenas appears to have been funded by the welding industry. (Ibid.) That study has not yet been published and is protected from discovery under numerous privileges.[2]

Rule 26(b)(2) provides that a court may deny discovery under the Federal Rules if the burden of the discovery outweighs its likely benefit, after taking "into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues." Here, the facts weigh heavily in favor of quashing the subpoenas. Most of the articles listed in the subpoenas appear to bear no relation to Plaintiffs' claims. The only article that does appear to be related to welding is a one page abstract. See Exh. A. to Subpoena, Sec. II.1.(d). Plaintiffs have not shown that the information sought is important to this litigation and the vast majority of the information sought does not appear to pertain to welding at all. This Court should protect the Institute from this abusive discovery under Rule 26(c).

D. Enforcement Of The Subpoenas May Chill Important Scientific Research.

Compliance with Plaintiffs' subpoenas will compromise the medical and research activities and reputation of The Institute. (Langston Decl. at ¶¶ 29-37) Compliance also will

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[2] The Institute has already produced to Plaintiffs, in response to a subpoena, the data underlying other studies regarding Parkinson's disease. It is unclear why Plaintiffs now seek additional information in a second subpoena directed towards the same party. Plaintiffs should not be permitted to harass the Institute in this manner. (Langston Decl. at ¶¶ 8-9)

take valuable resources and time away from important research and scientific work. The losers will be those members of the public who would otherwise benefit from this research.

Moreover, requiring the Institute to produce the data underlying pre-publication studies may have a a chilling effect in this area of scientific inquiry: "It is not unduly speculative to imagine that a large private corporation, through repeatedly securing broad-based subpoenas requiring total disclosure of all notes, reports, working papers and raw data relating to the ongoing studies, could make research in a particular field so undesirable as to chill or inhibit whole areas of scientific inquiry." Dow Chemical Co. v. Allen, 672 F.2d 1262, 1276 n.25 (7th Cir. 1982).

In Dow Chemical Co., Dow attempted to subpoena data and research related to toxicity studies being conducted by four University of Wisconsin researchers, in an effort to show that Dow's herbicides were safe. The district court refused to enforce the subpoenas and the Seventh Circuit upheld the decision. The Seventh Circuit found that "enforcement of the subpoenas would leave the researchers with the knowledge throughout continuation of their studies that the fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party whose interests were arguably antithetical to theirs." Id. Moreover, "production of raw research data, far in advance of the time that relevant and probative results could be expected, should not be compelled over the non-frivolous objections of the researchers." Id. at 1278.

Here, plaintiffs seek data from The Institute that relates to ongoing research. Premature disclosure of such data could jeopardize not only the research studies, but also the researchers' careers. Just as the Dow Chemical Court recognized the vital importance of maintaining the confidentiality of such studies in order to prevent any possible chilling of the First Amendment rights of researchers, this Court should do the same. The negative effect of the disclosure of The Institute's data is manifest and uncontradicted. (Langston Decl. At ¶¶ 29 – 37)

The Institute's research could yield nothing of value to Plaintiffs, yet they ask for an advance screening of The Institute's study. This is impermissible under the Court's general

discovery powers and this Court should therefore quash the subpoenas.

E. The Subpoenas Impermissibly Seek Expert Opinion From Unretained Experts.

"C]ompulsion to give evidence may threaten the intellectual property of experts denied the opportunity to bargain for the value of their services." FED. R. CIV. PROC. 45, advisory committee's note (1991).

In Mattel, Inc. v. Walking Mountain Productions, supra, the defendant in the action retained a San Francisco Museum of Modern Art (SFMOMA) curator as an expert witness. Mattel then subpoenaed non-party SFMOMA, demanding that SFMOMA produce all documents relating to this employee, the plaintiff, and Mattel's products. Mattel, 353 F.3d at 797-98. The district court quashed the subpoena, and the Ninth Circuit affirmed, holding that, even though the information sought was related to the litigation, it was an abuse of the subpoena power. Id. at 813-14.

In this case, we understand that one of the Ohio defendants has retained Dr. Goldman, a consultant to the Institute, as an expert witness. (Stone Decl. ¶ 16) But the Institute has not been retained by anyone. In Mattel, the non-party museum was the employer of a retained expert witness; but wide-ranging subpoenas served on the museum were quashed nonetheless as an abuse of the subpoena power.

F. The Information Sought Is Protected Against Disclosure By Health And Human Services Policy For Protection Of Human Research Subjects.

The Department of Health and Human Services (HHS) Policy for Protection of Human Research Subjects as set forth in the Code of Federal Regulations imposes standards of care for protection of human subjects in research studies. The HHS Policy provides in pertinent part:

> [t]his policy applies to all research involving human subjects conducted, supported or otherwise subject to regulations by any federal department or agency...[including] (1) Research that is conducted or supported by a federal department or agency....must comply with all sections of this policy. (2) Research that is neither conducted nor supported by a federal department or agency but that is subject to regulation [by receipt of an institution of HHS funds] must be reviewed and approved in compliance with ...this policy by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

45 CFR 46.101, et seq. The HHS Policy regulates federally funded or sponsored research projects that use human subjects. The regulations also require that any institution which receives HHS funds must supply HHS with an assurance that all research protocols involving human subjects conducted at that institution are reviewed to determine the propriety of the use of the human subjects. Because The Institute receives HHS funds (Langston Decl. ¶35), all research conducted by The Institute is subject to the HHS policy, regardless of whether the particular research project at issue receives federal funding.

The HHS regulations require that all research must be reviewed and approved by an institutional review board (IRB) that operates in accordance with the regulations. 45 CFR 46.101. The regulations require that there be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. 45 CFR 46.111(a).

Research is defined as "a systematic investigation designed to develop or contribute to generalized knowledge." A human subject includes any person about whom the researcher seeks (1) data through intervention or interaction with the individual or (2) identifiable private information. Private information includes information about which individuals have a reasonable expectation of privacy, such that the individual reasonably believes it will not be made public. 45 CFR 46.102.

Here, Plaintiffs are seeking privileged research information, including records of patients seen for research and underlying data for articles published or in the pre-publication stage. The data underlying these articles includes information contained in the Institute's patient database. (Langston Decl. at ¶¶ 18-20) Information in the database includes: the patient's ancestry; current age; medical conditions of parents, siblings and children; and age of death of parents, siblings and children; the patient's living arrangements, marital status, job title, number of years of employment, prior jobs and education; history of smoking, history of drinking alcoholic beverages, history of drinking caffeinated beverages, vision correction, psychological abnormalities, libido, skin, endocrine system, hematologic system, autoimmune system, cardiovascular system, pulmonary system, gastrointestinal system, urinary tract system and musculoskeletal

system. (Langston Decl. at ¶¶ 18 – 19)

The Institute keeps its medical research studies and data confidential. (Langston Decl. at ¶¶ 21-27) Because the HHS and FDA regulations also require that private information of the human subjects involved in research studies be kept confidential, the 2005 Subpoenas should be quashed.

G. HIPAA Regulations Prohibit Disclosure Of The Information Sought By The Subpoenas.

The Health Insurance Portability and Accountability Act of 1996 became effective April 14, 2003. 42 U.S.C.A. 1320(d) et seq. ("HIPPA "). One of the primary purposes of HIPAA was to protect the security and privacy of "individually identifiable health information." Congress gave the Department of Health and Human Services the task of creating national standards to ensure the integrity and the confidentiality of the information. The regulations created by the Department of Health and Human Services are known as the "Privacy Rule." The Privacy Rule establishes a patient's rights and requires that health professionals implement various procedures regarding the use of and access to individually identifiable health information. It prohibits covered entities from using and disclosing personal health information, except as required or permitted by the regulations.

Under 45 CFR 164.502(a), a covered entity, which includes a healthcare provider, may not use or disclose "protected health information," in any form, oral, written or electronic except as permitted under the Privacy Rule. "Use" includes examination of protected health information. "Disclosure" includes divulging or providing access to protected health information,

"Individually identifiable health information" is defined as:

> information that is a subset of health information including demographic information collected from and individual that is (1) created by the health care provider...and (2) relates to the past, present or future physical or mental health condition of an individual; the provision of health care to an individual; or with respect to which there is a reasonable basis to believe the information can only be used to identify the individual. 45 CFR 164.501

"Health information" is defined as:

> information, whether oral, or recorded in any form or medium, that (1) is created or received by a health care provider...school or university...and (2) relates to the past, present or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. 45 CFR 160.103

"Protected health information" is defined as:

> information, whether oral, or recorded in any form or medium, that (1) is created or received by a health care provider...school or university...and (2) relates to the past, present or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. 45 CFR 160.103

A covered entity must make reasonable efforts to limit the use of protected health information to the "minimum necessary" amount needed to accomplish the intended purpose of the use, disclosure or request. The disclosure of any further information, whether collateral or marginal, is prohibited.

These Privacy Standards demonstrate a strong federal policy of protection for patient health information. HIPPA preempts any contrary provisions of state law, other than those that provide more stringent protections. 45 CFR 1178(a)(1); 45 CFR 262(c)(2), In re PPA Litigation, 2003 WL 22203734, *2 (N.J.Super.L. 2003)

The information in The Institute's patient database includes "individually identifiable health information" and "protected health information" of patients seen for ongoing treatment and for research patients. Because the HIPAA regulations prohibit the disclosure of any such information, the subpoena should be quashed or a protective order refusing the discovery entered.

H. This Court Should Quash The Subpoenas Because Service Was Improper.

The subpoenas that form the subject of this motion are directed to "Custodian of Records" at the Institute. "Service of a subpoena upon a person named therein shall be made by delivering a copy thereof to such person . . . ." FED. R. CIV. PROC. 45(b)(1). Most courts interpret "delivering" to require personal service of the subpoena because, as with a

summons, a subpoena is a form of compulsory process. See Klockner Namasco Holdings Corp. v. Daily Access.com, 211 F.R.D. 685, 687 (N.D. Ga. 2002) (listing cases stating that either personal service or service by certified mail is sufficient under Rule 45(b).

Plaintiffs served these subpoenas upon a receptionist who was not authorized to accept service on behalf of The Institute or its custodian of records. Plaintiffs did not effect personal service on the Institute's agent for service of process, or effect service by certified mail, which are the two methods of service that satisfy Rule 45(b). Service is defective and this Court should quash the subpoenas.

IV.

CONCLUSION

For the foregoing reasons, The Institute respectfully submits that its motion to quash the subpoenas or enter a protective order denying the discovery be granted.

DATED: October 20, 2005

Respectfully submitted,

HOGE, FENTON, JONES & APPEL, INC.

By _____
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